

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF
PEDIATRICS, *et. al.*,

*

v.
Plaintiffs,

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* Civil No. 8:18-cv-883-PWG

FOOD AND DRUG
ADMINISTRATION, *et al.*,

*

Defendants.

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**BRIEF OF THE STATE OF MARYLAND
AS AMICUS CURIAE IN SUPPORT OF
PLAINTIFFS' OPENING BRIEF ON REMEDIES**

Pursuant to this Court's Standing Order 2018-07, the State of Maryland submits this brief in support of the Plaintiff's Opening Brief on Remedies. ECF No. 78, *Am. Acad. of Pediatrics v. FDA*, No. PWG-18-883 (D. Md. May 29, 2019). Maryland is home to thousands of teenagers and children who have used e-cigarettes that should have been subject to an FDA premarket review process but were not. The FDA has failed to conduct this premarket review since 2017, when it adopted the Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for the Industry (Revised) ("August 2017 Guidance"). As a result, many young Marylanders have developed a nicotine addiction that renders them more vulnerable to the risk of becoming cigarette smokers. These Maryland youth will suffer not only from the yet undetermined risks posed by e-cigarettes, but also from the myriad diseases inflicted by regular cigarettes. As these young Marylanders age and sicken, Maryland will incur medical expenses for

treating them through Medicaid. Therefore, Maryland has an interest in limiting youth exposure to e-cigarettes and thus in the FDA discharging its legal obligation to review these products for substantial equivalence as soon as possible. No party's counsel has authored this brief in whole or in part, and no party's counsel or other person contributed money that was intended to fund the preparation or submission of this brief.

ARGUMENT

Further Delay in the FDA's Premarket Review Will Harm Maryland by Permitting Electronic Vaping Products to Remain on the Market and "Attract New, Young Users."

"The surge in e-cigarette use by teenagers" that the Court noted in its Memorandum Opinion, ECF No. 73, *Am. Acad. of Pediatrics v. FDA*, No. PWG-18-883, 2019 WL 2123397 at *1 (D. Md. May 15, 2019), is consistent with Maryland's experience. The Maryland Department of Health tracks youth use of tobacco products through the Maryland Youth Risk Behavior Survey and the Youth Tobacco Survey. *See* Maryland Department of Health, The Maryland Youth Risk Behavior Survey & Youth Tobacco Survey – YRBS/YTS, <https://phpa.health.maryland.gov/ohpetup/Pages/YTRBS.aspx> (last visited June 11, 2019). The Department of Health found that in 2016, the most recent year for which it has published data, 35.3 percent of Maryland's high-school population had used an electronic vaping product,¹ and 13.3 percent had done so at least once during the 30

¹ The survey described electronic vapor products as "e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens [such as blu, NJOY, Vuse, MarkTen, Logic, Vapin Plus, eGo, and Halo]." Maryland Department of Health, 2016 Youth Risk Behavior Survey Results, Maryland High School Survey: Trend Analysis Report at 5, available at <https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%>

days before the survey.² More than 95 percent of high school vapers “use[d] a kind of flavoring other than tobacco flavor with an electronic vapor product.”³ The same survey also documented use of vaping products by middle school children: 8.4 percent had used a vaping product at least once, and 4.7 percent used vaping products at least once within the past 30 days.⁴

Youth e-cigarette use has increased since 2016. The National Youth Tobacco Survey showed that current e-cigarette use nationwide among high school students increased 78 percent between 2017 and 2018, from 11.7 percent to 20.8 percent.⁵ Karen A. Cullen et al., *Use of Electronic Cigarettes and Any Tobacco Product among Middle and*

20YRBS%20YTS%20Reports/2016MDH%20Trend%20Report.pdf (“Maryland High School Survey”).

² Maryland High School Survey at 5-6. Data for 2014 showed higher high school e-cigarette use within the last 30 days, at nearly 20 percent; the wording in the survey question may have led to a decline in responses from 2014 to 2016. See Maryland Department of Health, Monitoring Changing Tobacco Use Behaviors: Maryland 2000-2016 44 (State Fiscal Year 2017), available at <https://phpa.health.maryland.gov/Documents/CRF-Biennial-Tobacco-Study-FY-2017.pdf>.

³ Maryland High School Survey at 23.

⁴ Maryland Department of Health, 2016 Youth Risk Behavior Survey Results, Maryland Middle School Survey: Trend Analysis Report at 3-4, available at <https://phpa.health.maryland.gov/ccdpc/Reports/Documents/2016%20YRBS%20Reports/2016MDM%20Trend%20Report.pdf>.

⁵ The survey defined “current” tobacco product use as “a response greater than ‘0 days’ to the question, ‘During the past 30 days, on how many days did you use e-cigarettes?’” Karen A. Cullen et al., *Use of Electronic Cigarettes and Any Tobacco Product among Middle and High School Students — United States, 2011–2018*, 67 Morbidity & Mortality Weekly Rep. 1276 (2018), available at <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a5-H.pdf>.

High School Students — United States, 2011–2018, 67 Morbidity & Mortality Weekly Rep. 1276 (2018), available at <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a5-H.pdf>. Of those high school students who reported current e-cigarette use, 27.7 percent reported using e-cigarettes on 20 or more of the past 30 days, up from 20 percent in 2017. *Id.* Current e-cigarette use among middle school students nationwide increased 48 percent between 2017 and 2018, from 3.3 percent to 4.9 percent. *Id.*

Although the Maryland Department of Health has not yet published its 2018 data, estimating the likely growth in vaping by Maryland youth is not difficult. According to the Maryland Department of Education, 259,898 students were enrolled in public high schools in 2018. Maryland State Department of Education, 2018 Maryland School Report Cards, <http://reportcard.msde.maryland.gov/Graphs/#/Demographics/Enrollment/3/09,10,11,12/6/99/XXXX> (last visited June 11, 2019). If Maryland's teenagers vaped at a rate consistent with the national data, in 2018 approximately 54,000 Maryland public high-school students regularly used e-cigarettes that the FDA could and should have subjected to premarket review, absent the delay it introduced with the August 2017 Guidance.⁶ Nicotine's well-documented effect on the human brain will likely condemn most of these teenagers to decades or a lifetime of addiction. *See, e.g., United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 208-18 (D.D.C. 2006) (discussing addictive properties of nicotine), *aff'd in part and vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009).

⁶ 20.8 percent of 259,898 is 54,058.8.

Worse, Maryland youth who have become addicted to e-cigarettes currently on the market because of the August 2017 Guidance face an increased risk of becoming cigarette smokers. A study by the RAND Corporation found that youth who use e-cigarettes are more likely to start smoking cigarettes. Michael S. Dunbar et al., *Disentangling Within-and Between-Person Effects of Shared Risk Factors on E-cigarette and Cigarette Use Trajectories From Late Adolescence to Young Adulthood*, Nicotine & Tobacco Research, Oct. 2, 2018. Similarly, the Consensus Study Report of the National Academy of Sciences found that “[t]here is *substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.” National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* 532 (Kathleen Stratton et al. eds. 2018) (emphasis in original). In Maryland, that translates to data showing that “over half of youth [e-cigarette] users . . . also use traditional tobacco products.” Maryland Department of Health, Monitoring Changing Tobacco Use Behaviors: Maryland 2000-2016 48 (State Fiscal Year 2017), *available at* <https://phpa.health.maryland.gov/Documents/CRF-Biennial-Tobacco-Study-FY-2017.pdf>.

The adverse health effects of smoking combustible cigarettes are well-known. *See, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 188 (2000) (Breyer, J., dissenting) (noting the “wide consensus” about the adverse health effects of cigarettes). The health-care costs associated with smoking cigarettes are similarly well documented. In Maryland, those costs amounted to \$2.71 billion in 2014, the last year for which data is available. Centers for Disease Control and Prevention, *Best Practices for Comprehensive*

Tobacco Control Programs – 2014 98 (2014), available at https://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive_e.pdf. Maryland has a strong interest in preventing its youth from using e-cigarettes as a gateway to chronic use of combustible tobacco cigarettes. Maryland is a signatory to the 1998 Master Settlement Agreement, a landmark public-health agreement that imposes permanent injunctive relief and settlement payment obligations on numerous cigarette manufacturers, including some parties granted the right to file a consolidated *amicus curiae* brief in this case. *See Maryland v. Philip Morris Inc.*, 944. A.2d 1167, 1168-69 (Md. 2008). Maryland agrees with the Plaintiffs that the manufacturers of e-cigarettes have had ample notice that their products would be subject to premarket review. Further delay would expose Maryland’s youth and the State to unjustifiable risk of further harm. Therefore, Maryland urges this Court to enter Plaintiffs’ Proposed Remedial Order.

CONCLUSION

The Court should enter the Plaintiffs' Proposed Remedial Order.

Respectfully submitted,

BRIAN E. FROSH
Attorney General

/s/ John M. Leovy
JOHN M. LEOVY (Fed. Bar # 20803)
KIRSTIN LUSTILA (Fed. Bar # 02103)
Assistant Attorneys General
Office of the Attorney General
200 Saint Paul Place
Baltimore, Maryland 21202
(410) 576-7056 (tel.); (410) 576-6955 (fax)
jleovy@oag.state.md.us
klustila@oag.state.md.us